

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Vargas, Jaime et al.
Assignee: Cardica, Inc.
Title: Integrated Anastomosis System
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Menlo Park, California
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COMMISSIONER FOR PATENTS
Washington, D. C. 20231

SECOND PRELIMINARY AMENDMENT

Dear Sir:

Please substitute the enclosed drawing sheets, sheets 23 and 24 of 35, for sheets 23 and 24 of 35 as filed.

Please amend the specification as follows:

Specification, page 50, line 22 to page 51, line 18:

The expander tip 280 also includes an expander head 286 and an expander collet 287. Both the expander head 286 and the expander collet 287 have a larger diameter than the expander body 284, and extend substantially circumferentially around the expander tip 280. The expander head 286 is smoothly tapered from its distal end to its proximal end. Referring in particular to FIG. 28A, the expander head 286 includes a shoulder 288 at its intersection with the body 284 of the expander tip 280. The shoulder 288 forms an angle 290 with the surface of the body 284 of the expander tip 280. This angle 290 is substantially 95 degrees.

However, a different angle 290 may be utilized, if desired. The angle 290 is substantially the same around the entire expander tip 280. However, the angle 290 may vary in different locations around the expander tip 280. A lumen 292 extends through the expander tip 280, where that lumen 292 is substantially coaxial with the crown collar 202 and with the expander collar 276. The lumen 292 may itself taper to a smaller diameter toward the distal end of the expander head 286. This tapering acts to protect the graft vessel as it is pulled through the lumen 292. The tines 196 of the anastomosis device 140 are located distal to the distal end of the lumen 292. By tapering the lumen of the expander tip 280 to direct the graft vessel inward away from the tines 196 before that graft vessel is everted over them, the graft vessel is protected. The collet 287 is substantially circumferential around the expander tip 280, and is located proximal to the expander head 286. The collet 287 has a larger diameter than the body 284 of the expander 280. The collet 287 and the expander head 286 are translated relative to the crown 200 to deploy the anastomosis device 140 into a vessel wall, as is described in greater detail below.

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Specification, page 51, line 19 to page 52, line 8:

The expander tip 280 includes slots 294 defined therein. The slots 294 extend substantially axially from the distal end of the expander tip 280 through the expander head 286 and collet 287, extending proximally to the collet 287. The segments 289 of the expander tip 280 between the slots 294 are each biased outward relative to the axis of the expander tip 280, as may be seen most clearly in FIG. 28A. Alternately, the segments 289 are not biased outward relative to the axis of the expander tip 280. The slots 294 allow these segments 289 of the expander tip 280 to move inward toward the axis of the expander tip 280 at a point in the deployment of the anastomosis device 140 to allow the expander tip 280 to move proximally to the deployed anastomosis device 140. Thus, the slots 294 are sized to allow the

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segments 289 to move close enough to one another to allow the expander tip 280 to move proximally to the deployed anastomosis device 140. The outward force generated by the expander tip 280 acts to substantially center the anastomosis device 140 on the expander tip 280 during deployment, such that the axis of the anastomosis device 140 remains substantially coaxial with the axis of the expander tip 280.

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Specification, page 52, line 21 to page 53, line 4:

The segments 289 of the expander tip 280 between the slots 294 are each biased outward relative to the axis of the expander tip 280, as may be seen most clearly in FIG. 28A. This outward bias assists in deployment of the anastomosis device 140, as is described in greater detail below. Alternately, the segments 289 of the expander tip 280 between the slots 294 are not biased outward relative to the expander tip 280. Alternately, a ring (not shown) may be provided between the collet 287 and the expander head 286, or may be provided instead of the collet 287. The ring slides freely relative to the expander tip 280, and is used to compress the segments 289 toward the axis 143 of the anastomosis device 140 at the appropriate point in the deployment process.

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Specification, page 62, lines 7-20:

Referring also to FIG. 33, the spreader arms 168 and the outer flange arms 174 each begin to angle outward from the axis 143 after buckling at the intersections between them, under the effect of the continuing relative motion of the expander 260 and the crown 200. As seen in FIG. 32, the anastomosis device 140 continues to experience compressive stress, but at a lower level than at the point of buckling. The outward bias of the segments 289 of the expander tip 280 acts to axially center the anastomosis device 140 during deployment. Alternately, where the segments 289 are not biased outward, a ring (not shown) may encircle

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the body 284 of the expander tip 280 between the expander head 286 and the expander collet 287. The spreader arms 168 and outer flange arms 174 spread outward to deploy the outer flange 304, which is formed from the outer flange elements 173. The ring translates distally along the body 284 of the expander tip 280, urged in this direction by contact with the distal end of the crown 200. Distal motion of the ring causes the segments 289 to move radially. Thus, the crown 200 compresses the segments 289 with the ring.

Specification, page 64, line 12 to page 65, line 11:

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Compressive stress continues within the implant 142 after deployment, because the separated spreader arms 168 still exert a compressive force upon the deployed outer flange 304. The expander head 268 is still located distal to the body 302 of the implant 142 after the implant 142 has been deployed. The third and fourth cam paths 220, 221 are configured to translate the expander 260 distally after the implant 142 has separated from the discard section 144. The collet 287 is located at a position on the expander tip 280 such that the collet 287 enters the crown collar 202 shortly after the implant 142 has separated from the discard section 144. The outer diameter of the collet 287 is larger than the inner diameter of the crown collar 202. Thus, when the collet 287 moves into the crown collar 202, the collet 287 contracts, counteracting the outward biasing force exerted by the expander tip 280, and causing the expander tip 280 to radially contract. This radial contraction causes the expander head 286 to contract to an outer diameter substantially equal to the inner diameter of the body 302 of the implant, so that the expander tip 280 can translate distally through the body 302. At the time of collecting 325, the expander collet 287 causes the deployed implant 142 to experience a compressive force. After the expander tip 280 is collected down, compressive force again increases as the expander tip 280 translates proximally through the deployed implant 142. This compressive force reaches a maximum substantially at the time the

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expander tip 280 exits the proximal end of the body 302 of the implant 142, then quickly returns to zero as the integrated anastomosis tool 100 is removed from the implant 142. The profile of force over time as shown in FIG. 32 and described above is merely exemplary and qualitative, in order to describe one possible mode of operation of the integrated anastomosis tool 100 and the anastomosis device 140 deployed by that tool. The integrated anastomosis tool 100 and/or the anastomosis device 140 may be configured differently to result in a different force over time profile, if desired.

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Specification, page 65, lines 12-20:

Alternately, where the collet 287 is not used, the angle of the shoulder 288 is selected to cause deployment of the outer flange of the deployable section 142 and to compress the segments 289 together to allow the expander tip 280 to translate proximally away from the implant 140. In such an embodiment, the angle 290 of the shoulder 288 is substantially 65 degrees, but a different angle could be used. After the expander tip 280 has translated out of the body 302, the anastomosis is complete, and the integrated anastomosis tool 100 can be removed from the target vessel. The contact structure 110 has an open perimeter, so the integrated anastomosis tool 100 can be moved to one side such that the graft vessel can pass through the open portion of the contact structure 110.